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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,086	07/30/2001	Alan Ebringer	09262-027-51	2308

7590

06/30/2003

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EXAMINER

SCHEINER, LAURIE A

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/856,086

Applicant(s)

Ebringer, A.

Examiner

Laurie Scheiner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 31, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 6 is/are allowed Free of the  
Art of  
Record
- 6) ☒ Claim(s) 1, 3-5, and 7-10 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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Claims 1-10 are pending.

The disclosure is objected to because of the following informalities: claim 1 should be amended such that the acronyms (BSE), (MS) and (CJD) are replaced by bovine spongiform encephalopathy (BSE), multiple sclerosis (MS) and creutzfeld jacob disease (CJD), respectively.

Appropriate correction is required.

Claim 7 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

Claims 8 and 10 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The myelin and/or myelin, neurofilaments and *Acinetobacter calcoaceticus*, as claimed, has the same characteristics and utility as that found in nature and therefore does not constitute patentable subject matter. In the absence of the hand of man, the naturally occurring compositions are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, mere isolation of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426 (1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273 F. Supp. 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co., 283 US 1 (1931); Funk Brother Seed Co. v. Kalo Inoculant Co., 283 US 127 (1984). Amending the claims to comport with a proper article of manufacture is suggested.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 8-10, a kit claim is essentially a composition claim comprising a container means. However, the claims as instantly recited fail in reciting a container means or compartmentalized carrier; also, the compositions of claims 8 and 10 are not isolated and therefor read on a person or bovine and/or a person or bovine infected with (or carrier of) *Acinetobacter calcoaceticus*.

Claim 5 is of improper dependent form in its reciting "the test antigen" at line 1. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebringer et al. (Environmental Health Perspectives, Vol. 105, No. 11, November 1997, pp. 1172-1174). or Ebringer (WO 98/13694).

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Claim 1 is drawn to a method for diagnosing spongiform or demyelinating diseases in vertebrates which comprises assaying a biological sample for antibodies which bind to myelin or parts thereof.

Ebringer et al. and Ebringer are cumulative in teaching the assaying of a biological sample for anti-*Acinetobacter* antibodies. Moreover, the references teach that *Acinetobacter* sp. exhibits molecular mimicry of antigens of the nervous system (e.g. myelin or myelin fragments) of mammals. Cattle exposed to *Acinetobacter* thus produce antibodies that bind with *Acinetobacter* antigens but also with self antigens (i.e., cross-reactivity); please see Ebringer et al. ( p. 1173, column 1, paragraph 3) and Ebringer (abstract, page 2, last paragraph to page 3, paragraph 1). As such, the references anticipate that which is claimed since assaying an antibody which binds *Acinetobacter* also assays antibodies which bind myelin or an antigenic peptide that exhibits molecular mimicry of a mammalian myelin peptide, due to cross-reactivity. Thus, the methods of the references necessarily function in accordance with the instant limitations of the claim since the respective method steps of the references are identical to instant method steps despite the preamble. The diagnostic test of Ebringer detects the same antibodies as the diagnostic test of instant claim 1. Again, the reference sets forth that the detected antibodies cross-react with myelin (page 2, last paragraph). Applicants are reminded that the preamble of the claim is not given patentable weight and it is well established that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner

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can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.



Laurie Scheiner/LAS  
June 23, 2003

  
**LAURIE SCHEINER  
PRIMARY EXAMINER**